A Clean Set of Claims

1. An in vitro immunoassay method for diagnosing human gastric intestinal metaplasia which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human gastric intestinal metaplasia.

30. (New) An in vitro immunoassay method for diagnosing human colonic type gastric intestinal metaplasia which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with a monoclonal antibody DAS-1, or a fragment thereof, wherein the monoclonal antibody is produced by a hybridoma deposited under ATCC accession number HB 9397 and reacts with a human gastric intestinal metaplasia antigen, and wherein the gastric tissue sample is not a gastric cardia; and

(b) detecting immunoreactivity between the gastric tissue sample and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

31. (New) The method according to claim 30, wherein the human gastric intestinal metaplasia antigen is a colon epithelial specific protein.

32. (New) The method according to claim 30, wherein the monoclonal antibody or the fragment thereof is directly attached to a detectable label.

33. (New) The method according to claim 30, wherein detecting immunoreactivity is performed by an immunoperoxidase staining, an immunofluorescence, an immunoelectronmicroscopy, or an ELISA.

34. (New) The method according to claim 33, wherein the immunoassay method is an immunoperoxidase staining.

35. (New) The method according to claim 34, wherein the immunoperoxidase staining comprises:

(a) deparaffinizing the gastric tissue by heating;

(b) immersing the deparaffinized tissue in xylene;

(c) rehydrating the tissue in decreasing concentrations of alcohol;

C2 (d) washing the rehydrated tissue in neutral PBS;

(e) reducing the aldehydes of the washed tissue of step (d);

(f) reacting the tissue with normal goat serum, the monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex;

(g) treating the reacted tissue with diaminobenzidine;

(h) washing the diaminobenzidine-treated tissue;

(i) staining the washed tissue of step (h) with hematoxylin, eosin or both; and

(o) examining the stained tissue under a microscope to detect the presence of immunoreactivity.

36. (New) The method according to claim 35, which further comprises the step of trypsinizing the gastric tissue after reducing the aldehydes in the tissue but

before reacting the tissue with the normal goat serum, the monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex.

37 (New). The method according to claim 35, wherein the decreasing concentrations of alcohol used for rehydration are 100%, 95%, 70%, and 50% alcohol.

38. (New) The method according to claim 30, further comprising the step of performing a negative control assay on a negative control sample to detect cells in the gastric tissue sample of the subject suspected of having human colonic type gastric intestinal metaplasia and comparing results of the gastric tissue sample with the results of the negative control sample, wherein the presence of human colonic type gastric intestinal metaplasia cells in the gastric tissue sample over the absence of human colonic type gastric intestinal metaplasia cells in the negative control sample indicates a positive diagnosis of human colonic type gastric intestinal metaplasia.

40. (New) The method according to claim 30, further comprising the step of performing a positive control assay on a positive control sample to detect human cells of colonic type gastric intestinal metaplasia present in the positive control sample.

41. (New) An in vitro immunoassay method for screening for human colonic type gastric intestinal metaplasia, wherein reactivity with a monoclonal antibody DAS-1 is indicative of a predisposition for gastric carcinoma, which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, wherein the monoclonal antibody DAS-1 is produced by the hybridoma deposited under ATCC accession number HB 9397 and reacts with a human gastric intestinal metaplasia antigen, and wherein the gastric tissue is not a gastric cardia; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

42. (New) The method according to claim 41, wherein the human gastric intestinal metaplasia antigen is a colon epithelial specific protein.

43. (New) The method according to claim 41, wherein the monoclonal antibody or the fragment thereof is directly attached to a detectable label.

44. (New) The method according to claim 41, wherein detecting immunoreactivity is performed by an immunoperoxidase staining, an immunofluorescence, an immunoelectromicroscopy, or an ELISA.

45. (New) The method according to claim 41, wherein the immunoassay method is an immunoperoxidase staining.

46. (New) The method according to claim 45, wherein the immunoperoxidase staining comprises:

(a) deparaffinizing the gastric tissue by heating;

(b) immersing the deparaffinized tissue in xylene;

(c) rehydrating the tissue in decreasing concentrations of alcohol;

(d) washing the rehydrated tissue in neutral PBS;

(e) reducing the aldehydes of the washed tissue of step (d);

(f) reacting the tissue with a normal goat serum, the monoclonal antibody, a biotinylated goat anti-mouse antibody and an avidin-biotin-peroxidase complex;

(g) treating the reacted tissue with diaminobenzidine;

(h) washing the diaminobenzidine-treated tissue;

(i) staining the washed tissue of step (h) with hematoxylin, eosin or both; and

examining the stained tissue under a microscope to detect the presence of immunoreactivity.

47. (New) The method according to claim 46, which further comprises the step of trypsinizing the gastric tissue after reducing the aldehydes in the tissue but before reacting the tissue with the goat serum, the monoclonal antibody, the biotinylated goat anti-mouse antibody and the avidin-biotin-peroxidase complex.

48. (New) The method according to claim 46, wherein the decreasing concentrations of alcohol used for rehydration are 100%, 95%, 70%, and 50% alcohol.

49. (New) The method according to claim 46, further comprising the step of performing a negative control assay on a negative control sample to detect cells in the gastric tissue sample of the subject suspected of having human colonic type gastric intestinal metaplasia and comparing results of the gastric tissue sample with the results of the negative control sample, wherein the presence of human colonic type gastric intestinal metaplasia cells in the gastric tissue sample over the absence of human colonic type gastric intestinal metaplasia cells in the negative control sample indicates a positive diagnosis of human colonic type gastric intestinal metaplasia..

50. (New) The method according to claim 66, further comprising the step of performing a positive control assay on a positive control sample to detect human cells of colonic type gastric intestinal metaplasia present in the positive control sample.